INL/EXT-16-37593

Achieving Quality Compliance for Sodium-Cooled Fast Reactor Metallic Fuels Information

George Honma

March 2016

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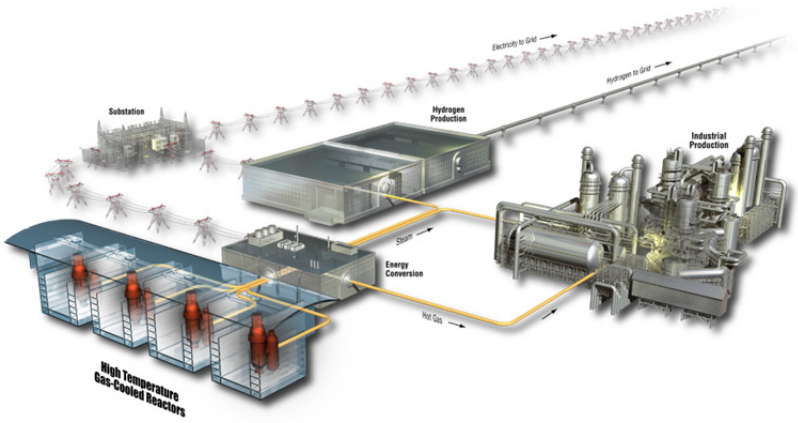

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Achieving Quality Compliance for Sodium-Cooled Fast Reactor Metallic Fuels Information

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SUMMARY

This document identifies and discusses implementation elements that can be used to facilitate consistent and systematic evaluation processes relating to quality attributes of technical information (with focus on sodium-cooled fast reactor [SFR] technology) that will be used to support licensing of advanced reactor designs. Information may include, but is not limited to, design documents for SFRs, research and development data and associated documents, test plans and associated protocols, operations and test data, international research data, technical reports, and information associated with past United States Nuclear Regulatory Commission reviews of SFR designs.

The approach for determining acceptability of test data, analysis, and/or other technical information is based on guidance provided in INL/EXT-15-35805, *Guidance on Evaluating Historic Technology Information for Use in Advanced Reactor Licensing.* The process outlined in this document can be adopted into a working procedure by national laboratories performing data qualification, or by applicants seeking future license application for advanced reactor technology.

Managing the data generated by large research and development projects presents a significant challenge for retaining data integrity and availability. Thus, it is important that collected data be stored in a controlled and secure electronic environment (i.e., database system). Stored data should provide traceability and document qualification status. The database system should also have means to maintain identification and traceability of the data throughout the life of its use. Therefore, it is important that the database developer identify and implement the applicable quality assurance requirements for a data management system. American Society of Mechanical Engineers Standard NQA-1 2008, Subpart 2.7, "Quality Assurance Requirements for Computer Software for Nuclear Facility Applications," provides applicable requirements.

Development of this document is based on guidance provided in American Society of Mechanical Engineers Standards NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," and NQA-1a-2009, Addenda to ASME NQA-1-2008, as endorsed by Nuclear Regulatory Commission Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," which provide fundamental quality assurance requirements for satisfying 10 CFR 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

CONTENTS

SUMMARY vii

ACRONYMS xi

DEFINITIONS xii

1. PURPOSE 1

2. APPLICABILITY 1

3. INSTRUCTIONS 1
   - 3.1 Data Qualification 1
   - 3.2 Identifying Need to Qualify Data 2
   - 3.3 Categorizing Types of Data 2
     - 3.3.1 Type A Data (Data Collected Within NQA-1 QA Program) 2
     - 3.3.2 Type B Data (Data Collected Within NQA-1 QA Program that are not Intended for Design or Licensing Applications Use) 2
     - 3.3.3 Type C Data (Data Collected Outside NQA-1 QA Program or are not Known) 2
   - 3.4 Evaluating Data 2
     - 3.4.1 Establishing Evaluation Team 3
     - 3.4.2 Preparing Documentation 3
     - 3.4.3 Selecting Qualification Methods 3
     - 3.4.4 Evaluating Data Set and Documenting Results 3
     - 3.4.5 Determining Conclusion 3
   - 3.5 Approving Data 4
     - 3.5.1 Approval 4
     - 3.5.2 Deficient 4
     - 3.5.3 Concurrence 4

4. QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR DATA MANAGEMENT SYSTEM 4

5. RECORDS 4

Appendix A Process for Data Qualification 5

Appendix B Guidance on Types of Data/Information to Consider for Review 7

Appendix C Guidance for Determining Qualification Methods 9

Appendix D Data Evaluation Form 15

FIGURE

Figure A-1. Process for Data Qualification. 6

ACRONYMS

DOE	Department of Energy
M&TE	measuring and test equipment
NRC	Nuclear Regulatory Commission
QA	quality assurance
R&D	research and development
SFR	sodium-cooled fast reactor
V&V	verification and validation

DEFINITIONS

Deficient qualification data (set). Data (set) that fail to meet applicable requirements with no clear traceability. Therefore, the data do not satisfy NQA-1 requirements.

Indeterminate quality. Sources of data with a non-NQA-1 QA program or sources with an unknown QA program.

Qualified data. Data that have been collected and managed under an approved NQA-1 QA program. Alternatively, data that have been gathered and managed under requirements that meet the intent of an NQA-1 QA program and have been reviewed, verified, and documented by a data evaluation team to meet the requirements for a specific end use as defined in a data collection plan. Any nonconformances have been evaluated and determined to not affect the usability of the data.

Subject matter expert. A knowledgeable individual whose skill and/or experience establish him or her as an expert in a specific subject.

Trend data. Data that may not meet all requirements for Type A or Type C data, yet due to the data set attributes and/or content, provide some value for an intended use.

Types of data. Data are categorized into three types for planning and management purposes as follows:

1. Type A–Data collected within an NQA-1 QA program that meet specific requirements for data use. Intended use is defined. Data collectors must verify that test requirements were met. Independent verification may be used to ensure that all other requirements were met. These data are used by the program to support nuclear materials and facilities design and licensing and are collected within an NQA-1 QA program. This category includes such data that are collected from irradiation performance testing, out-of-pile materials testing, and experimental verification of the SFR fuel. The qualification of these Type-A supporting data elements must be addressed in the data collection plan and data qualification process.
2. Type B–Data collected within an NQA-1 QA program that are not intended or needed to support nuclear materials and facility design and licensing activities. These data are considered for information only.
3. Type C–Data collected outside an NQA-1 QA program or not known that have a defined intended use. Evaluation is required to verify that the controls were in place as part of the data planning, collection, and storage processes that compare to NQA-1 applicable requirements. Data meeting all requirements may be qualified for intended use under an appropriate procedure. Data gathered by foreign partners to the program may be gathered under an International Organization for Standardization-9001 or other equivalent QA system. These data could be qualified by showing that the QA processes were functionally equivalent to NQA-1 processes.

Unevaluated Data. Data that have not yet been evaluated with respect to applicable QA requirements.

Achieving Quality Compliance for Sodium-Cooled Fast Reactor Metallic Fuels Information

1. PURPOSE

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2. APPLICABILITY

The process outlined in this document is based on guidance provided in American Society of Mechanical Engineers Standards NQA-1-2008, "Quality Assurance Requirements for Nuclear Facility Applications," and NQA-1a-2009, Addenda to ASME NQA-1-2008, as endorsed by NRC Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction)," which provide fundamental quality assurance (QA) requirements for satisfying 10 CFR 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants.

Technical information that is used in safety design and licensing decisions should have traceability to appropriate quality standards. A record of the quality standards that were applied at that time tests were performed and data were generated should be maintained with technical information. This includes items such as design control, control of instructions, procedures, drawings, test control, measuring and test equipment control, and records.

Also, it should be noted that implementing QA requirements as prescribed in Department of Energy orders for meeting QA requirements may be found to be acceptable if endorsed by the NRC. For example, during the preapplication review of the sodium advanced fast reactor, the NRC reviewed and endorsed QA standards in DOE O 5700.6B, "Quality Assurance," dated September 23, 1986, for conceptual review. This is furthered discussed in NUREG-1369, "Preapplication Safety Evaluation Report for the Sodium Advanced Fast Reactor (SAFR) Liquid–Metal Reactor." Therefore, it is important to assess each quality standard that was applied in historic Department of Energy information against NRC-endorsed standards. It should be noted that NQA-1-2008 and NQA-1a-2009 are the current NRC-endorsed American Society of Mechanical Engineers standards for NQA-1. Prior NRC NQA-1 endorsements included NQA-1-1994 and NQA-1-1984. Furthermore, NRC staff did not endorse all of the updates and addendums to NQA-1 in the past.

3. INSTRUCTIONS

3.1 Data Qualification

Appendix A, Figure A-1, provides the process for data qualification. As discussed in Section 2, if it is uncertain whether the data meet a QA program that has been previously reviewed and approved by the

NRC, or collected data lacks associated supporting QA documentation, then the data should be evaluated in accordance with the following subsections.

3.2 Identifying Need to Qualify Data

The evaluation process should identify a specific need for qualifying the data (i.e., define a scope, end use, impact on risk, safety and mission of the review. Appendix B provides guidance on the types of data to consider for review. The data subject to review are then categorized according to Subsection 3.3.

3.3 Categorizing Types of Data

The data that are subject for review are categorized by types of data *(see def.)* according to a method(s) addressed in the following subsections.

3.3.1 Type A Data (Data Collected Within NQA-1 QA Program)

Data collected within an NQA-1 QA program, as a minimum, should be evaluated to determine whether data were collected under a previously NRC-reviewed and -approved version of NQA-1. As stated in Section 2, NRC staff has not endorsed all updates and addendums to NQA-1. If uncertainties exist whether the data meet a QA program that has been previously reviewed and approved by the NRC, then the data should be evaluated using the qualification process outlined in Subsection 3.4.

NOTE: *During the preapplication review of the sodium advanced fast reactor liquid metal reactor, the NRC reviewed the QA program imposed on design control activities by DOE O 5700.6B, dated September 23, 1986, and determined that the conceptual design and eight criteria of NQA-1-1983 were applicable to the scope of work. Review results are documented in NRC NUREG-1369, dated December 1991.*

3.3.2 Type B Data (Data Collected Within NQA-1 QA Program that are not Intended for Design or Licensing Applications Use)

This type of data include unevaluated data *(see def.)* and data that fit the definition of Type B data. No provision has been made to evaluate this type of datum.

3.3.3 Type C Data (Data Collected Outside NQA-1 QA Program or are not Known)

Data from sources without an NQA-1 QA program or that are not known require evaluation to determine whether or not they can be used in nuclear applications. Subsection 3.4 addresses how to evaluate this type of datum.

NOTE: *Sometimes testing activities are sent to outside entities, such as universities, to be performed. These entities may perform sound research but will normally not have an NQA-1 compliant QA program. Occasionally, resulting data collection and analysis prove to be useful in steering design requirements or are used in support of reactor design. To minimize the risk associated with outside entities selected to perform testing activities with a potential for use in design-related work, selected NQA-1 quality requirements should flow down in the contract or statement of work that will support data collection and analysis. Implementation of those quality requirements by the outside entity will support a data qualifying evaluation to determine whether it can be used in nuclear applications.*

3.4 Evaluating Data

For data collected within an NQA-1 QA program (Type A) and data collected outside an NQA-1 QA program (Type C), follow the guidance provided in this subsection.

3.4.1 Establishing Evaluation Team

An evaluation team should be established that consists of, at a minimum, a technical lead, QA engineer, subject matter expert *(see def.)* (e.g., fuel engineer, safety analysis engineer, design engineer, R&D research engineer), and project manager. The project manager of the organization performing the evaluation should select the technical lead. The technical lead should be selected based on the appropriate knowledge level of the data being evaluated. The technical lead should select the QA engineer and subject matter expert. The size of the team may expand to meet the demands of a more complex review of the data set.

3.4.2 Preparing Documentation

The evaluation should be documented. The Data Evaluation Form provided in Appendix D can be used for this purpose. The Data Evaluation Form provides evidence of the evaluation and also provides a quality record of the evaluation.

The requestor of the evaluation should complete the preparer information and Section 1 of the Data Evaluation Form.

The technical lead should document the team members in Section 2 of the Data Evaluation Form.

3.4.3 Selecting Qualification Methods

The method(s) that will be used to evaluate both the QA program equivalence and data (data set) should be selected from Appendix C. Any one or combination of methods addressed in Appendix C may be used to qualify a data set. The method(s) that best applies to the data set under evaluation should be selected.

The following should be documented in Section 3 of the Data Evaluation Form:

- Method(s) selected for evaluating the data set, including the applicable QA program if available
- Rationale for the selected method(s).

If the data were collected outside an NQA-1 QA program, it should be determined if the data can be evaluated to meet QA program equivalence requirements as discussed in Appendix C.

It is recommended that if the collected data come from a single test or R&D effort, a batch review be performed rather than evaluate individual datum (i.e., review as data set). For example, if a fuel test was performed to collect multiple test data under a single test condition with the same QA standards, then the collected data can be most efficiently evaluated as a data set.

3.4.4 Evaluating Data Set and Documenting Results

The qualification criteria for evaluating the data (or data sets), including the QA program (if available) that was established in Subsection 3.4.3, should be documented in Data Evaluation Form.

The result of the evaluation should be documented in Section 4 of the Data Evaluation Form. It should also include rational by which the data set meets selected qualification criteria, including discussion on how the data meet or do not meet applicable criteria.

Applicable supporting information used during the evaluation process (e.g., applicable QA program, applicable sections of NRC NUREG 1369, and test plans) should be attached to the Data Evaluation Form.

3.4.5 Determining Conclusion

A final review of evaluation results should be performed and the overall results documented in Section 5 of the Data Evaluation Form. When performing the review it should be determined whether the data:

- Met all requirements. The data (data set) are considered qualified.
- Met some of the requirements. The data may meet an application use as trend data *(see def.)*. Data set approval for limited-use will depend on conditions identified by the evaluation team.
- Do not meet enough requirements and should not be approved for use. Considered indeterminate quality *(see def.)* and should not be used for future design and licensing activities.

3.5 Approving Data

3.5.1 Approval

The technical lead, QA engineer, subject matter expert (if applicable), and licensing engineer should document approval, including limited-use approval, in Section 6 of the Data Evaluation Form. Any limits on data use should be documented on the form prior to signing.

3.5.2 Deficient

The technical lead and QA engineer should document that the data are not useable and the reasoning for disapproval in Section 7 of the Data Evaluation Form.

3.5.3 Concurrence

The project manager should ensure that all decisions are performed by personnel qualified and authorized to evaluate data under prescribed conditions. The project manager should document concurrence with all decisions and report content in Section 8 of the Data Evaluation Form.

4. QUALITY ASSURANCE REQUIREMENTS FOR NUCLEAR DATA MANAGEMENT SYSTEM

Managing the data generated by large R&D projects presents a significant challenge for retaining data integrity and availability. Thus, it is important that collected data be stored in a controlled and secure electronic environment (i.e., database system). Stored data should provide traceability and document qualification status. The database system should also have means to maintain identification and traceability of the data throughout the life of its use.

Therefore, it is important that the database developer identify and implement the applicable QA requirements for a data management system. NQA-1-2008, Subpart 2.7, “Quality Assurance Requirements for Computer Software for Nuclear Facility Applications,” provides applicable quality standards.

5. RECORDS

Data Evaluation Form and any attachments

Data (data set) reviewed

Supporting information used for evaluation

Appendix A

Process for Data Qualification

Appendix A

Process for Data Qualification

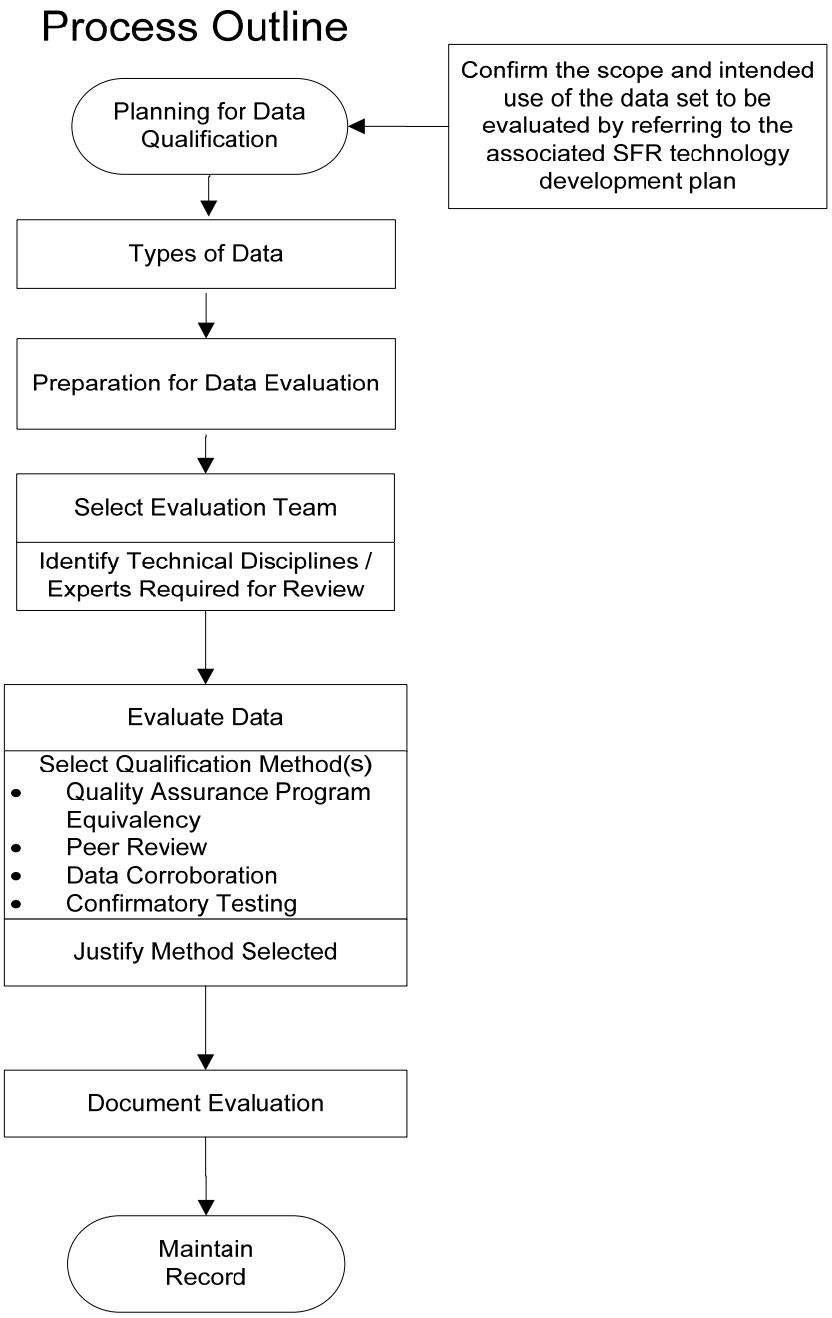

Figure A-1. Process for Data Qualification.

Appendix B

Guidance on Types of Data/Information to Consider for Review

Appendix B

Guidance on Types of Data/Information to Consider for Review

Data/Information to Consider	Possible Data/Information Location
Brief description of experiment objectives and data collected	Data collection plan; summarized in plan.
End use of data and requirements	Data collection plan; summarized in plan.
Provenance of materials being tested or analyzed	Specification for material purchase, chain of custody on material, drawing for machining specimen or details of subsampling, labeling of specimen.
Testing and analysis procedures	References to American Standards for Testing and Materials methods and revision numbers, description of specific procedures. Any deviations from procedures; justification for deviations.
Measurement equipment, conditions, and personnel qualification	Identification of instruments used in data collection; records of instrument calibration that environmental conditions conform with method specifications, of training of people performing testing.
Data reduction and analysis procedures	Calculations performed to determine parameters in engineering units from millivolt reading of instruments; additional modeling or analysis calculations to obtain parameters from raw measurements (e.g., curve fitting and computer simulations).
Data reduction calculations, software, and methods; input on data sets, parameterization of simulation codes	Reference to software quality assurance plans and documentation of software testing results. Independent confirmation that calculations were performed correctly. Confirmation that reduced data for reporting and analysis are traceable to data taken from instrument.
Assessment of results from any quality control samples; identification of any audits or assessments conducted	Results from measurements of standards or replicated measurements on specimens. Audits or assessments conducted, audit/assessment findings, corrective actions taken if needed.
Analysis of data for anomalies and outliers	Description of outliers and anomalies, assessment of implications for data set. Assessment of usability of data. Control charts, correlation graphs, coefficient of variation calculations.
Discussion of any problems identified in data and corrective actions taken.	Instrument drift may be gradual and predictable, so reanalysis of data to account for drift may result in defensible data. Discussion of correction methods sufficient to demonstrate effectiveness of adjustment needed.
Conclusions about whether data met requirements for intended use	Summarized requirements in data collection plan; discuss how requirements were met.
Identification of any trend or failed data explicitly (by specimen, analysis, or instrument and date range)	Tables or appendixes of data that do not meet requirements. Failed data should not be discarded but kept for future evaluation to determine cause. Failed data also provides means for statistically trend analysis.
Analysis and interpretation of data	Analysis and interpretation depends on data report being generated. Data report objective is to document that data are suitable for intended use and not as an analysis report. However, report can serve multiple purposes and could contain analysis and interpretation.
Data	For small data packages, report could contain a copy of all data collected. For irradiation monitoring of data streams where millions of data points are collected, reporting all the data is not practical.

Appendix C

Guidance for Determining Qualification Methods

Appendix C

Guidance for Determining Qualification Methods

C-1 INTRODUCTION

Qualification methods recognized in the nuclear industry provide a means for evaluating data sets and establishing how and to what extent data may be used in design or licensing activities. Each method has inherent advantages that prescribe their application in the evaluation process. These methods may be used singularly or in any combination that establishes the value of the data for the intended use and addresses risks, concerns for safety, and impact to intended use.

The following four methods are identified as nominally applicable for use in evaluating and qualifying data: (1) quality assurance (QA) program equivalence, (2) peer review, (3) data corroboration, and (4) confirmatory testing.

The application of these methods is determined by the level of credibility and identified intended use of the data from the American Society of Mechanical Engineers NQA-1 perspective. Data collected outside an NQA-1 QA program environment requires additional review to establish testing, documentation, and preservation methods. Data collected under an NQA-1 QA program may also require evaluation to qualify the data for an intended use.

C-2 DATA OF INDETERMINATE QUALITY *(SEE DEF.)* OR SOURCES OF DATA WITH NON-NQA-1 QA PROGRAMS

Data from sources of indeterminate quality or sources without an NQA-1 QA-based program should be subjected to a QA equivalence review prior to considering any data from these sources for use in design or licensing activities. Other methods listed may be used in addition to QA equivalence, as needed, to establish data credibility and application to an intended use.

C-3 ACCEPTANCE REQUIREMENTS

Objective evidence is required for any method selected to support a qualification demonstrating compliance to the requirements of that method. Documents that support the qualification should be attached to the Data Evaluation Form.

C-4 QUALIFYING METHODS

C-4.1 QA Program Equivalence Method

C-4.1.1 General Information

The Department of Energy (DOE) has promulgated its overarching QA expectations and requirements in orders issued by the Department. From 1981 to 1999, DOE O 5700.6, "Quality Assurance," was in effect. From 1999 to present, DOE O 414.1D, "Quality Assurance*,"* serves as the current set of baseline QA requirements across the DOE complex. QA programs at each DOE site were/are expected to implement these orders based on risk and using a graded approach to tailor the QA requirements to the activities being conducted and the intended use of the final results/deliverables. Under each of these orders, DOE encouraged its sites to adopt consensus standards that would more fully describe the detailed quality stipulations necessary to conduct activities, including nuclear research and development (R&D).

A wide-ranging review of QA requirements incumbent upon national laboratories conducting nuclear R&D activities over the last 35 years reveals a wide gamut of expectations concerning QA rigor by DOE based on considerations such as program or project needs, the types of technical activities conducted, and

the safety of DOE nuclear facilities. Review also provides evidence of the consistent invocation of the requirements of various versions of NQA-1 to be used in regulating nuclear research activities. As previously stated, the Nuclear Regulatory Commission endorsed the use of NQA-1-1984, NQA-1-1994, and NQA-1-2008. Starting in 1994, NQA-1 included Part IV, Subpart 4.2, Guidance on Graded Application of Quality Assurance (QA) for Nuclear-Related Research and Development, to provide further implementation information based on the life-cycle of each nuclear R&D effort. This subpart proved useful to many contractors, including Idaho National Laboratory, Pacific Northwest National Laboratory, and Oak Ridge National Laboratory, in implementing flexible QA programs based on NQA-1, but appropriately attenuated to meet the needs of an R&D environment.

The methodology for determining equivalency is the same as used to conduct a QA audit. Checklists based upon each applicable element of NQA-1 should be established. The requirements as they are defined in NQA-1-2008 and NQA-1a-2009 should form the basis for these checklists. It is essential that each requirement of NQA-1 be included in each checklist. Some requirements may apply and some may not, but the checklists should contain every requirement and reflect the evaluation team's best judgment concerning what requirements should be applied to the final body of data under review.

It should be noted that not all of the 18 QA criteria identified in NQA-1 may be applicable during the R&D phase of the project. Therefore, it is the responsibility of the QA organization (e.g., Argonne National Laboratory) implementing this process to confirm the applicable QA criteria. As a minimum, the specific NQA-1 criteria addressed in the following subsections should be considered for the QA program equivalence method.

C-4.1.2 NQA-1 Criteria that Should Be Considered for QA Program Equivalence Method

C-4.1.2.1 Organization

Site-level documents in place at the time the data were generated need to be reviewed to determine what, if any, standard was invoked for site-wide QA implementation. This type of documentation would also provide site-wide systems and processes used in QA implementation for a wide range of issues such as material control, equipment calibration, records retention, and many more. If activities were conducted in a nuclear facility, then there may be facility-based documents that provide information necessary to ascertain the QA program in place. Further, nuclear programs and projects have historically operated through distinct and singular QA program plans that would further define what requirements were invoked and implemented in producing the data set under review. These types of sources would also provide information concerning the QA infrastructure in place at the time the data were generated.

Other desirable information would include a description of the role of QA personnel in the organization, any oversight activities that may have been conducted, and any established hold-points where QA approval may have been required prior to further work proceeding. These types of hold-points are especially prevalent in situations where experimental activities moved from a non-reactor to a reactor environment.

The organization that produces the data, also creates, maintains, and provides a description of the organization involved with producing the data set. Sufficient detail should be provided to recognize titles and responsibilities of all those involved with producing the data set.

C-4.1.2.2 Test Planning, Implementation, and Documentation (Research Planning)

Where applicable, test methods and characteristics should be planned and documented and the approaches and procedures recorded and evaluated. Characteristics should be tested, and test methods specified. Test results should be documented and their conformance to acceptance requirements evaluated.

Sufficient documentation should be developed to ensure replication of the work. The researcher/developer should document work methods and results in a complete and accurate manner. The level of documentation should be sufficient to withstand a successful peer review. Protocols on generation and safeguarding of data and process development from research should be developed if needed for consistency of R&D work.

For example, if an outside agent (e.g., university) is used to collect test data, then the outside agent should submit a test plan/research plan to the funding organization for review and concurrence prior to use if requested. Laboratory notebooks should be controlled by outside agent procedures/processes. Also, the process for development of intellectual property documentation should be controlled under outside agent document control procedures/processes.

C-4.1.2.3 Equipment Calibration and Documentation

The researcher should specify the requirements of accuracy, precision, and repeatability of measuring and test equipment (M&TE). Where standard M&TE procedures are not used, the effects of the instrument's performance on the uncertainty of the measurements and tests should be considered in the research. During the process development stage and for all R&D support activities, M&TE should be controlled. The degree of control should depend on the application of the measurement. However, calibration records documenting instrument calibration to a national standard should be maintained.

C-4.1.2.4 Procurement Document Control

If final results of the work are expected in the next stage of the work and if the pedigree of material being used could influence the usefulness of the results of the work during research, procurement document specifications should be controlled appropriately. For development and support activities, the level of procurement document control should be applied to support a commercial design basis (i.e., engineering design system criteria).

For example, if an outside agent is used to collect data, procurement document control requirements, including material pedigree records, should be provided as a deliverable product.

C-4.1.2.5 Training and Personnel Qualification

Personnel performing R&D activities should be qualified in accordance with the required training requirements. .

C-4.1.2.6 Analysis/Modeling Software Verification and Validation

The following requirements may be applicable:

- Software used for modeling development in support of scoping work will have configuration control implemented by a minimum of a "frozen" copy of a software executable file plus a text statement describing chronological changes being made. At a minimum, all changes will be verified to operate correctly by the developer and a second checker prior to use.
- Reports or work summaries for modeling software development should include:

  A. Software name

  B. Version number

  C. Computer manufacturer name and model

  D. Name and version of operating system

  E. List of libraries or interfaces/environments required for correct software operation

  F. Reference to the applicable verification and validation (V&V) documentation.

- Modeling should be performed using codes and/or software packages that have received appropriate and documented V&V in accordance with procedures/processes. The code or software version(s) used to develop results should be identified in the project's final report.

  Where codes or models have not received appropriate V&V, or the V&V documentation is not available, the outside agent should provide a description of the model or code and the tools and methods used to ensure accuracy of the data generated.

NQA-1-2008, Part II, Subpart 2.7, Quality Assurance Requirements for Computer Software for Nuclear Facility Applications, conveys a comprehensive set of requirements appropriate for consideration in evaluating software developed for this effort.

Technical personnel with help from QA subject matter experts should clearly document each requirement that applies, those that do not apply, and how each applicable requirement is addressed in the current software development and deployment process.

C-4.1.2.7 Records

In many cases, the notebook or journal of the researcher is the QA record. These documents should be controlled in accordance with controlled procedures/processes as needed (e.g., maintain notebook as a controlled document or maintain copies of critical pages or access-controlled filing when not in use to preserve process repeatability and the QA record). Electronic media may be used to record data and should be subject to appropriate administrative controls for handling and storage of data.

C-4.1.2.8 Data Acquisition/Collection and Analysis

When gathering data, the researcher should ensure that the systems and subsystems of the experiment are operating properly. Software systems used to collect data and operate the experiment require verification that they meet functional requirements prior to collection of actual data. Data anomalies require investigation. When performing data analysis, define: assumptions and the methods used, the results obtained (for evaluation by competent experts), how data were interpreted, methods used to identify and minimize measurement uncertainty, the analytical models used, and whether the R&D results have been documented adequately that can be validated.

C-4.1.2.9 Control of Special Processes

Any special processes involved with producing the data set should be identified. Lists of equipment, documented processes, and any controls essential in operating and maintaining the process(es) should be included.

NOTE: *Other requirements may also apply as determined by the evaluation team. This method should result in an assessment of the demonstrated data producer QA program capabilities based on the team-selected requirements or criteria.*

C-4.2 Peer Review Method

The peer review method is the process of subjecting data to the scrutiny of subject matter experts in the same field. The intent of this review is to compare the data and data controls against subject matter criteria. If successful, the data will add to the knowledge base for the identified or intended use. Objectives for this method would typically include answering the following questions:

- Is the employed test methodology acceptable?
- Do data collection/development match expected approaches?
- Have the data been used in a similar range of applications?
- Do the data support application to the defined intended use?

The evaluation should include the following requirements:

- Test plans
- Uncertainty analysis, including the extent to which uncertainties affect interpretations, conclusions, and data validity
- Data interpretation adequacy and applicability
- Identification of and resolution to data anomalies.

C-4.3 Data Corroboration Method

The data corroboration method may be used to establish validity of a data set through comparison to other qualified data *(see def.)* sets. Requirements may include identifying sufficient data sets to permit valid statistical comparison. Inferences drawn to corroborate data should be clearly identified, justified, and documented. This effort should produce a report describing how the data were corroborated.

C-4.4 Confirmatory Testing

The confirmatory testing method may be used when tests can be designed and performed to establish the quality of data. Confirmatory testing may also be required when previous testing results are not verifiable as a result of questionable testing methodology or a lack of applicable documentation. Limited extrapolation is acceptable. Confirmatory testing requires at least one or more independent tests that reproduce(s) a comparable data set. All tests that attempt to re-create the subject data set should be included in the evaluation for confirmatory testing.

Appendix D

Data Evaluation Form

Appendix D

Data Evaluation Form

Preparer(s)	Name	Phone No.	Name	Phone No.

SECTION 1—DATA SOURCE DESCRIPTION

Data ID	Date

Technical and Subject Matter Disciplines Required to Evaluate Data

SECTION 2—EVALUATION TEAM
(Add additional members as an attachment if necessary.)

Technical Lead	Name:	E-mail	Phone No.

Description of Experience and Skills that Pertain to Evaluating this Data Set

Project Manager	Name	E-mail	Phone No.

Description of Experience and Skills that Pertain to Evaluating this Data Set

Quality Engineer	Name	E-mail	Phone No.

Description of Experience and Skills that Pertain to Evaluating this Data Set

SECTION 3—QUALIFYING METHODS
Quality Assurance Program Equivalence Method (Criteria)
Peer Review (Criteria)
Data Corroboration (Criteria)
Confirmatory Testing (Criteria)

SECTION 4—EVALUATE DATA SET	
Qualifying Criteria	Evidence and How Well it Meets Criteria

SECTION 5—EVALUATION CONCLUSIONS

SECTION 6—APPROVAL			
Technical Lead	Date	QA Engineer	Date
Subject Matter Expert (if needed)	Date	Licensing Engineer	Date

SECTION 7—DEFICIENT			
Technical Lead	Date	QA Engineer	Date

SECTION 8—CONCURRENCE	
Project Manager	Date

Instructions for Completing Data Evaluation

Preparer Information

. Initiator of Data Evaluation Form: Enter the preparer name and phone number.

Section 1—Data Source Description

Initiator of Data Evaluation Form: Complete Section 1 as follows:

A. Enter a unique number (or identifier) assigned to the data being reviewed for qualification in the Data Identification No. box.

B. Enter the date when the evaluation was started in the Date box.

C. Enter a brief description of the data being evaluated in the Brief Data Description.

Section 2—Evaluation Team

. Technical Lead: Complete Section 2 by entering the information requested on the form for all team members.

Section 3—Qualifying Methods

. Complete Section 3 by identifying one or more of the following methods to use for qualifying the data (see Appendix C for a detailed description of each method):

- Quality assurance (QA) program equivalence method
- Peer review
- Data corroboration
- Confirmatory Testing.

Section 4—Evaluation Data Set

. Provide documented evidence of the evaluation, including qualifying criteria used and evidence of how it meets the criteria. Examples for completing the Evidence and How Well it Meets Criteria block are as follows:

Example No. 1

If "Qualifying Criteria" is met by American Society of Mechanical Engineers Standard, then the Evidence and How Well it Meets Criteria block should reference the appropriate section of the American Society of Mechanical Engineers Standard and how it met that criteria.

Example No. 2

If "Qualifying Criteria" is met by DOE O 5700.6B, "Quality Assurance," dated September 23, 1986, then the Evidence and How Well it Meets Criteria block should provide (1) a detailed discussion of which of the eight criteria* of NQA-1 were applied during the scope of work; (2) references to the QA plan and other applicable implementing QA information; and (3) reference to Nuclear Regulatory Commission (NRC) NUREG 1369, "Preapplication Safety Evaluation Report for the Sodium Advanced Fast Reactor (SAFR) Liquid–Metal Reactor." These references should be provided since QA program requirements for DOE O 5700.6B were previously reviewed and accepted by the NRC.

******The eight criteria of NQA-1 1983 reviewed by the NRC included:*

1. Organization
2. Quality Assurance Program
3. Design Control
4. Instructions, procedures, and drawings
5. Document Control

6. Corrective Action
7. Quality Assurance Records
8. Audits

The NRC Staff has already reviewed the sodium-cooled fast reactor-*related documents listed below to evaluate the degree to which the QA requirements in Chapter 17.1 of NUREG 0800 were satisfied:*

- 149QPP000001, dated 4/1/87, SAFR Quality Assurance Plan
- AI-DOE-13527, Rev. 13, (pgs. G 373-377), Responses to NRC Questions on the OA Program
- DOEO 57000, 6B, dated September 23, 1986, Quality Assurance
- 149QP1000001, dated March 3, 1987, SAFR Quality Assurance Program Matrix
- 149APQ000001, dated January 19, 1987, SAFR Quality Audit Planning
- QAOP N1.02, dated March 26, 1982, RI Procedure Quality Assurance Manual. Procedures, and Instructions
- QAOP N1.04, dated December 16, 1983, RI Procedure Quality Assurance Audits
- QAOP N1.21, dated October 10, 1980, Quality Assurance Plans
- Gavigan (DOE) to Morris (NRC) dated 6/18/87, transmitting Quality Assurance Program information
- EMP-3-63, dated May 1, 1984, Documentation, Release and Control of Engineering Computer Programs
- A-500, dated January 20, 1986, Rocketdyne Operating Policies and Procedures
- J-500, dated January 10, 1986, Quality Program
- J-500. 1, dated August 27, 1986, Quality Program Audits

The precedents established by these and other related documents should be actively considered during data set evaluations that involve sodium-cooled fast reactor *information.*

Section 5—Evaluation Conclusions

Provide an overall conclusion based on the evaluation performed, providing documented evidence of whether the data meet (or does not meet) the applicable QA requirements based on the evaluation.

Section 6—Approval

Technical Lead, QA Engineer, Subject Matter Expert (if needed), and Licensing Engineer: If the data reviewed meet the applicable QA requirements, document approval, including limited-use approval, in Section 6. Document any limits on the data in Section 6.

Section 7—Deficient

Technical Lead and QA Engineer: If the data do not meet the applicable QA requirements, document the data as deficient and the reasoning for disapproval in Section 7.

Section 8—Concurrence

Project Manager: Document concurrence with all decisions and report content in Section 8.